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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/664,715
Filing Date: September 18, 2003
Appellant(s): MANOUSSAKIS ET AL.

Mark Lindsey
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed May 31, 2011 appealing from the Office action mailed April 29, 2010.

(1) Real Party in Interest

The examiner has no comment on the statement, or lack of statement, identifying by name the real party in interest in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The following is a list of claims that are rejected and pending in the application:

Claims 1-14, 16-18, 20-24, 26-28, 30-86 are pending.

Claims 14, 16-18, 20-24, 26-28 and 30-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hugh Conway (EP 1 107 002 A2).

(4) Status of Amendments After Final

The examiner has no comment on the appellant's statement of the status of amendments after final rejection contained in the brief.

(5) Summary of Claimed Subject Matter

The examiner has no comment on the summary of claimed subject matter contained in the brief.

(6) Grounds of Rejection to be Reviewed on Appeal

The examiner has no comment on the appellant's statement of the grounds of rejection to be reviewed on appeal. Every ground of rejection set forth in the Office action from which the appeal is taken (as modified by any advisory actions) is being

maintained by the examiner except for the grounds of rejection (if any) listed under the subheading "WITHDRAWN REJECTIONS." New grounds of rejection (if any) are provided under the subheading "NEW GROUNDS OF REJECTION."

(7) Claims Appendix

The examiner has no comment on the copy of the appealed claims contained in the Appendix to the appellant's brief.

(8) Evidence Relied Upon

EP 1 107 002 A2	CONWAY	06-2001
US 4,101,422	LAMONT	07-1978

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 14, 16-18, 20-24, 26-28 and 30-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hugh Conway (EP 1 107 002 A2), published June 13, 2001.

Conway teaches a container (tube 14) having an upper end 13, a closed lower end 14, and a sidewall 15 between the upper and lower ends 13, 14 having inner and outer walls 15a, 15b (see paragraphs [0022]). The tube includes a pierceable closure (stopper 18) therein.

Conway teaches a thixotropic gel 24 contained in a deformable container or flexible bag 22. The gel and bag are formed to create first 22b and second 22a continuous regions as seen in Figs. 1 to 3. Conway teaches the first region of the bag and gel is located at or adjacent the lower end 14a and the second region 22a

extending upward from a portion of the first region 22b, wherein the first region comprises an imaginary upper boundary at which the first region exhibits 360° circumferential contact with the inner wall 14a, and wherein the first region comprises at least about 80 vol.% of the thixotropic gel. That is, as shown in the Figs. 1 and 2, Conway teaches the device is formed so that the gel 24 substantially fills the first lower portion 22b of the bag 24 with only remaining second upper portion 22a being substantially absent of gel (see paragraph [0028]). Thus, it can be reasonably assumed that the first region of the gel comprises *at least about* 80 vol.% of the thixotropic gel. Further, providing an upper second region 22a of gel that extends upward toward the open end of the tube from the first lower region 22b promotes initiation of gel movement at lower centrifugation speeds than would otherwise be required and enhances gel movement between the lighter phase and heavier phase components of blood upon centrifugation.

Conway does not specifically disclose the gel in contact with a portion of the inner wall of the container. However, the use of thixotropic gel materials as a direct barrier for moving into an area adjacent the two phases of the sample being separated in order to maintain the components separated for subsequent examination of the individual components is well known in the art (see paragraphs [0002]-[0005] of Conway). Conway teaches the most widely used devices include thixotropic gel material such as polyester or silicon gels (see paragraph [0004] of Conway). Appellant's specification recognizes that such thixotropic gels directly used in separating blood components are typically considered chemically inert to most analytes present in

blood samples, see paragraph [0033] of appellant's specification as discussed further below. Thus, it would have been obvious to one of ordinary skill in the art at the time of the claimed invention to eliminate the flexible bag from the device of Conway since the use of such bags increases the manufacturing cost and complexity of the device.

As to claim 16, it appears the imaginary upper boundary of Conway exhibits a best fit plane within 10 degrees of a plane perpendicular to the longitudinal axis of the tube, see Figs. 2-3.

Regarding claims 17 and 18, Conway is silent to the distance between the first and second regions being between 8 to 21 mm, however, the claimed distance would have been obvious to one of ordinary skill in the art through routine experimentation in an effort to optimize the operational parameters of the device.

As to claims 20-24, it is reasonable to assume the first region 22b of Conway comprises about 80 to 95 vol. % of the gel (claim 20), the interior surface of the thixotropic gel at the intersection of the first and second regions exhibits a radius of curvature between about 4 and about 8 mm (claim 21), wherein a best-fit plane to the exposed surface of the first region facing the interior of the container exhibits an angle of 25 ° or less with a plane substantially perpendicular to the longitudinal axis of the container (claim 22), the exposed surface of the second region facing the interior of the container defines a best-fit plane exhibiting a 45 to 90° angle with a plane substantially perpendicular to the longitudinal axis of the container (claim 23), the best-fit plane to the exposed surface of the first region facing the interior of the container exhibits an angle of 90 to 140° with the best-fit plane to the surface of the second region facing the

interior of the container (claim 24), wherein along a plane perpendicular to the longitudinal axis of the container located halfway between the average height of the exposed surface of the first region and the uppermost point of the second region (see Figs. 1-3).

As to claims 26 and 27, the second region 22a of Conway exhibits 80 to 140° circumferential contact with the inner surface, wherein the entirety of the second region exhibits less than 180° circumferential contact with the inner wall 15a and, wherein the entirety of the second region 22a exhibits less than 120° circumferential contact with the inner wall 15a, see in particular Figs. 1 and 2 of Conway.

(10) Response to Argument

In response to the previous rejection of claims 14, 16-18, 20-24, 26-28 and 30-32 under 35 U.S.C. 103(a) as being unpatentable over Hugh Conway (EP 1 107 002 A2), hereinafter "Conway", appellant argues that Conway teaches away from the use of a thixotropic gel in direct contact with a blood sample or the separated components. Appellant also asserts that if the proposed modification would render the prior art invention unsatisfactory for its intended propose, then there is no suggestion or motivation to make the proposed modification (see MPEP 2143.01 (V)).

The examiner respectfully disagrees that Conway teaches away from the use of a thixotropic gel in direct contact with container and blood sample. In addition, the examiner respectfully disagrees that the proposed modification (i.e., elimination of the bag from the Conway device) would render the device inoperable for its intended purpose. The intended purpose of Conway is to provide an assembly for separating a

fluid sample into a higher specific gravity phase and a lower specific gravity phase using a flowable separation medium for moving adjacent the two phases of the sample being separated under centrifugal force in order to maintain separation of the heavier and lighter factions of fluid sample. In particular, manufacturing the device so that it provides an upper second region 22a of flowable separation medium that extends upward toward the open end of the tube from the first lower region 22b promotes initiation of the flowable separation medium movement at lower centrifugation speeds than would otherwise be required and enhances gel movement upon centrifugation resulting in faster separation between the two phases of blood sample. The examiner summits that the absence of a bag containing the thixotropic gel material would not prevent the thixotropic gel in Conway from readily flowing at lower centrifugation speeds and establishing a physical separation between the phases of blood sample. This is because the practice of such placing thixotropic gels in direct contact with the separated blood components for providing a physical separation between the separated fluid phases is well known in the art (see paragraphs [0002]-[0004] of Conway).

Paragraph [0004] in Conway states (emphasis added):

> "The most widely used device includes thixotropic gel material such as polyester or silicone gels. The present gel serum separation tubes require special manufacturing equipment to prepare the gel and to fill the tubes. Moreover, the shelf-life of the product is limited in that over time unbound resin may be released from the gel mass. This resin may have a specific gravity that is less than or equal to the separated serum and may

float in the serum and may clog the measuring instruments such as the instrument probes used during the clinical examination of the sample collected in the tube..."

While the Conway reference stresses the use of a bag to prevent clogging and "possible" chemical interaction of thixotropic gel with the blood sample, it does not "teach away" from the direct use of thixotropic gel for establishing a physical separation between the separated fluid phases. The examiner submits that the totality of the prior art must be considered, and proceeding along with accepted wisdom in the art is evidence of obviousness. While the examiner recognizes that a prior art reference that "teaches away" from the claimed invention is a significant factor to be considered in determining obviousness, however, "the nature of the teaching is highly relevant and must be weighed in substance. A known or obvious composition does not become patentable simply because it has been described as somewhat inferior to some other product for the same use." In re Gurley, 27 F.3d 551, 554, 31 USPQ2d 1130, 1132 (Fed. Cir. 1994) (Claims were directed to an epoxy resin based printed circuit material. A prior art reference disclosed a polyester-imide resin based printed circuit material, and taught that although epoxy resin based materials have acceptable stability and some degree of flexibility, they are inferior to polyester-imide resin based materials. The court held the claims would have been obvious over the prior art because the reference taught epoxy resin based material was useful for applicant's purpose, applicant did not distinguish the claimed epoxy from the prior art epoxy, and applicant asserted no discovery beyond what was known to the art.). See MPEP § 2145, subsection D. 1.

The examiner submits that thixotropic gels used in separating blood components are considered by the prior art to be chemically inert to most analytes present in blood samples. As discussed above, Conway teaches at paragraph [0004], "[t]he most widely used device includes thixotropic gel material such as polyester or silicon gels." Consider that appellant states at paragraph [0033] of appellant's specification (emphasis added):

> "A variety of separator gels, known in the art, are capable of being advantageously used in the invention. See, e.g., U.S. Pat. Nos. 4,101,422, 4,148,764, and 4,350,593. In particular, acrylic-based, polyester-based, and hydrocarbon-based gels have all been found to be of use as separator materials, where such gels typically contain a resin modified with a particle such as fumed silica in order to form a networked gel."

Further, Appellant specifically cites the polyester-based separator gels in US Patent No. 4,101,422 to Lamont, as known in the art and capable of being used in appellant's own invention. The separator gel in used in the Lamont reference, for example, is a polyester-based thixotropic gel in direct contact with the blood sample. See col. 2, lines 32-34 of Lamont, wherein Lamont specifically teaches "[t]he polyester-based compositions are not affected by contact with the blood and they do not alter the blood components." (Emphasis added). Lamont further teaches that such gels are known and accepted in the prior art as inert (see col. 2 lines 46-50 of Lamont). Thus, if the polyester-based thixotropic gels used in the instant invention do not clog the measuring instruments and are chemically inert to the blood components, it is

reasonable to assume the polyester-based thixotropic gels disclosed in Conway also would not clog the measuring instruments and are chemically inert to the blood components when placed in direct contact with the blood sample. Consequently, the examiner submits that it would have been obvious to one of ordinary skill in the art at the time of the claimed invention to eliminate the flexible bag from the device of Conway since the use of such bags increases the manufacturing cost and complexity of the device.

Appellant also argues that Conway fails to specifically disclose at least the claimed feature of the first region comprising at least about 80 vol. % of the gel. Appellant further argues that since Conway does not indicate the drawings are to scale, thus, the proportions of features in the drawing are of little value. Appellant acknowledges that paragraph [0028] referring to Figs. 1 and 2 of Conway discloses that the gel 24 substantially fills the first portion 22b (i.e., first region) of the bag 24 with only remaining second portion 22a (second region) being collapsed and substantially absent of gel, but Appellant asserts that one cannot reasonably conclude as to what the term "substantially" means in relation to vol. % of gel.

While the examiner agrees that the Conway disclosure did not indicate that the drawings were to scale, it is well established that the description of the article pictured can be relied on, in combination with the drawings, for what they would reasonably teach one of ordinary skill in the art. See MPEP 2125. The description of the Conway device at paragraph [00028] with respect to Figs. 1 and 2, states the gel 24 fills only a portion 22b (i.e., first region) of bag 22 with remaining portion 22a (second region), i.e.,

of the bag being collapsed and substantially absent of gel. The examiner asserts that this description in combination with drawings shown in Figures 1 and 2 would reasonably teach one of ordinary skill in the art that the first region (22b) comprises at least 80 vol. % of the thixotropic gel. In addition, the term "substantially" in the phrase "substantially absent" suggests “for the most part or essentially absent of gel”. Lastly, the limitation that the first region comprises at least 80 vol.% of the gel suggest that the first region can comprise all of the gel (i.e., 100 vol.%).

Thus, for the reasons delineated above, the claim remain rejected over the prior art.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner’s answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

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